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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,138	06/27/2003	Stephen P. LaBerge		1137

38169 7590 09/16/2009

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EXAMINER	
MCMILLIAN, KARA RENITA	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/604,138	LABERGE, STEPHEN P.	
	Examiner	Art Unit	
	KARA R. MCMILLIAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *2 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-27-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending.

Election/Restrictions

Applicant's election without traverse of an acetylcholine esterase inhibitor as a species of a class of substances that intensify REM sleep in the reply filed on April 2, 2009 is acknowledged.

Applicant's election with traverse of huperzine A as a specific species of an acetylcholine esterase inhibitor in the reply filed on April 2, 2009 is acknowledged. The traversal is on the grounds that at least insofar as donepizil, rivastigmine, galantamine, tacrine, and huperzine A, a search of said compounds would not be burdensome on the Examiner since said compounds share a common empirical formula as well as an NH2 amine functional group. This argument is not found persuasive because Applicants claim many other species of Acetylcholinesterase inhibitors besides said compounds that do not have the same empirical formula such as metrifonate. Furthermore the claims are not limited to only donepizil, rivastigmine, galantamine, tacrine, and huperzine A, rather any acetylcholine esterase inhibitor that intensify REM sleep which can be any acetylcholine esterase inhibitor. Thus a search for any acetylcholine esterase inhibitor that intensify REM sleep including all claimed species of acetylcholine esterase inhibitors are considered burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2 and 6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 1, 3-5 and 7-10 are being examined as they read on the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, Applicants claim amphetamine derivatives however, Applicants do not disclose what the derivatives of amphetamine are. As such, it is unclear what is meant by amphetamine derivatives. Accordingly, claim 10 is rendered indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raynie et al. U.S. Patent No. 5,551,879 in view of Hedner et al. U.S. Patent No. 6,034,117.

Raynie et al. teach that lucid dreaming is the ability to be aware of the experience of dreaming, while in a dream state and that this phenomenon occurs when an individual in the dream state, and without awakening, realizes that he/she is dreaming (see column 1 lines 12-16). Raynie et al. teach that becoming lucid while dreaming is in itself an exhilarating experience and may be used for educational purposes and that the problem with lucidity is that it often occurs on its own with little or no means of consciously inducing or controlling this state while dreaming (see column 1 lines 44-48). Raynie et al. teach an apparatus for the detection of rapid eye movement (REM) during sleep to help induce lucid dreaming (see column 1 lines 36-38). Raynie et al. further teach that the REM state of sleep offers a benefit for learning to become lucid in REM sleep (see column 1 lines 52-54). Thus Raynie et al. teach that the ability to experience lucid dreaming occurs during REM sleep.

Raynie et al. further teach that different methods and techniques have been developed to help the induction of lucid dreaming including chemical compounds like DMAE (2-dimethylaminoethanol) which hold the user at a higher level of consciousness while sleeping (see column 1 line 60 to column 2 line 6). Raynie et al. teach an apparatus or device that helps to induce lucid dreaming, equipped with a REM detector

which checks for REM about once every minute and is thus less likely to miss REM activity (see column 3 lines 12-14).

Raynie et al. do not teach the administration of an acetylcholinesterase inhibitor to enhance the frequency and intensity of lucidity in dreaming.

Hedner et al. teach that central nervous acetylcholinergic mechanisms are intimately involved in the regulation of wakefulness and sleep, particularly rapid eye movement (REM) sleep (see column 3 lines 10-13). Hedner et al. further teach that systemic administration of acetylcholinesterase inhibitors in humans produce an increase in REM sleep and a shortening of the latency from sleep onset to the first episode of REM sleep (see column 3 lines 19-21). Hedner et al. further teach numerous examples of acetylcholinesterase inhibitors such as physostigmine, velnacrine, huperzine A, etc. (see column 3 line 45 to column 5 line 8).

Accordingly, one of ordinary skill in the art at the time of the instant invention would have found it obvious to combine the teachings of Raynie et al., which teach that the ability to experience lucid dreaming occurs during REM sleep, with the teachings of Hedner et al., which teach that the administration of acetylcholinesterase inhibitors produce an increase in REM sleep and a shortening of the latency from sleep onset to the first episode of REM sleep. Thus, since acetylcholinesterase inhibitors produce an increase in REM sleep and a shortening of the latency from sleep onset to the first episode of REM sleep, it would be obvious to one of ordinary skill in the art that the administration of an acetylcholinesterase inhibitor would enhance the frequency and intensity of lucidity in dreaming since the period in which lucidity in dreaming occurs,

REM sleep, would be increased and the amount of time needed to reach REM sleep would be shortened, thus increasing the frequency of REM sleep episodes. Furthermore, it would be obvious to one of ordinary skill in the art that if the period of time during REM sleep is increased, the period of time of lucid dreaming would also be increased, resulting in longer or more frequent lucid dreams thus increasing the intensity of the lucid dream.

Regarding claim 3, it would be obvious to administer the drug at bedtime since lucidity in dreaming occurs during sleep and specifically during REM sleep. Regarding claim 4, it would be obvious to combine an acetylcholine esterase inhibitor with a device as claimed by Raynie et al. that enhances lucidity in the dream state that occurs during REM sleep since the device enhances lucidity during REM and the acetylcholinesterase inhibitor will increase REM thus increasing the frequency and intensity of lucid dreams. Claim 10 is rendered obvious based upon the rationale presented above that if REM sleep is increased by acetylcholinesterase inhibitors such as huperzine A, lucid dreaming would also be enhanced since lucid dreaming occurs during REM sleep. Furthermore it would be obvious to employ said methods in individuals wherein REM sleep is shortened since it would be expected that lucid dreaming would also be decreased since REM sleep is shortened and lucid dreaming occurs during REM sleep. Thus it would be obvious to increase REM sleep in individuals who have shortened REM sleep in order to enhance and intensify REM sleep.

Conclusions

Claims 1, 3-5 and 7-10 are rejected. Claims 2 and 6 are withdrawn. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is (571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/
Examiner, Art Unit 1617

KRM

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617